K081699

1071

510K) SUMMARY

DATE
June 13, 2008

AUG 29 2008

PRODUCT, CLASSIFICATION NAME
Trade name: Planmeca Sovereign
Common name: Dental unit with patient chair
Classification: EIA, Class I
Regulation number: 872.6640 + 872.6250

MANUFACTURER
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UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)
Planmeca USA Inc.
100 North Gary Avenue, Suite A
Roselle, IL 60172
Phone: (630) 529 2300
Fax: (630) 529 1929
Contact person : Bob Pienkowski

INTENDED USE
Planmeca Sovereign is a dental operative unit, which is an AC-powered device that is intended to supply power to and serve as a base for other dental devices and accessories. The device includes a dental patient chair, which is intended to properly position a patient to perform different dental procedures. The device is to be operated and used by dentists and other legally qualified professionals

PRODUCT DESCRIPTION
The Planmeca Sovereign is a dental operative unit including a dental patient chair. The design is very flexible with many motorized functions, and both left-handed and right-handed use is easily obtainable. The dentist and assistant are allowed to change their working postures according to the operation to be performed. The versatile swivelling enables fluent two-handed and four-handed treatment sequences. The unit is equipped with a digital control system with graphical user interface (GUI) to offer ease-of-use. The instrument console includes six instrument locations, with easy instrument interchange.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2008

Mr. Bob Pienkowski
Managing Director
Planmeca USA, Incorporated
100 North Gary Avenue, Suite A
Roselle, Illinois 60172

Re: K081699
Trade/Device Names: Planmeca Sovereign
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: August 19, 2008
Received: August 22, 2008

Dear Mr. Pienkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Samuel Lin for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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K081699

Indications for Use

510(k) Number (if known):

Device Name: Planmeca Sovereign

Indications For Use:

Planmeca Sovereign is a dental operative unit, which is an AC-powered device that is intended to supply power to and serve as a base for other dental devices and accessories. The device includes a dental patient chair, which is intended to properly position a patient to perform different dental procedures. The device is to be operated and used by dentists and other legally qualified professionals.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081699